



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 28, 2014

Toshiba Medical Systems Corporation
% Mr. Orlando Tadeo
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K141459

Trade/Device Name: Aplio 500/400/300 Diagnostic Ultrasound System, V5.0
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 2, 2014
Received: October 3, 2014

Dear Mr. Tadeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio 500/400/300 Diagnostic Ultrasound System, V5.0, as described in your premarket notification:

Transducer Model Number

| | | |
|------------|------------|------------|
| PST-25BT | PST-30BT | PST-50BT |
| PST-65AT | PVT-375BT | PVT-375SC |
| PVT-375MV | PVT-382BT | PVT-382MV |
| PVT-661VT | PVT-781VT | PVT-674BT |
| PVT-675MV | PVT-675MVL | PVT-681MV |
| PVT-712BT | PVT-745BTF | PVT-745BTH |
| PVT-745BTV | PVT-770RT | PLT-604AT |
| PLT-704AT | PLT-704SBT | PLT-705BT |
| PLT-705BTF | PVT-705BTH | PLT-805AT |

| | | |
|-------------|------------|------------|
| PLT-1005BT□ | PLT-1202S | PLT-1204BT |
| PLT-1204BX | PLT-1204MV | PET-508MA |
| PET-510MB | PET-512MC | PET-805LA |
| PC-20M | PC-50M | |

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141459

Device Name

Aplio 500/400/300 V5.0 Diagnostic Ultrasound System

Indications for Use (Describe)

The Diagnostic Ultrasound System Aplio 500 Model TUS-A500, Aplio 400 Model TUS-A400 And Aplio 300 Model TUS-A300 is indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial) and laparoscopic.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

System: Aplio 500, Aplio 400, Aplio 300 V5.0

Transducer: _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|---------------|----------------------|-----|--------------|-------|--------|----|--------------------------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | P | P | 2 | P | P | P | | P | 5,7,8, 9,10,14,18 |
| Abdominal | P | P | P | P | P | 2,3 | P | P | P | | P | 5,7,8, 9,10,11,12,14, 15,16,18 |
| Intra-operative (Abdominal) | P | P | P | | P | 2 | P | P | P | | | 4,5,7,11 |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | N | N | N | | N | 2 | N | N | N | | | 5,7 |
| Pediatric | P | P | P | P | P | 2,3 | P | P | P | | P | 5,7,8,9,10,12,14,15, 18 |
| Small Organ (Note 1) | P | P | P | | P | 2 | P | P | P | | | 4,5,6,7,8,9,10,11,14, 15,17,18 |
| Neonatal Cephalic | P | P | P | P | P | 3 | P | P | P | | | |
| Adult Cephalic | P | P | P | P | P | 3 | P | P | P | | | |
| Trans-rectal | P | P | P | | P | 2 | P | P | P | | P | 4,5,7,11,12,18 |
| Trans-vaginal | P | P | P | | P | 2 | P | P | P | | P | 4,5,7,11,12,18 |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | P | P | | | 4,5,6,7,8,9,10,11,14, 15,17,18 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | P | P | | | 4,5,6,7,8,9,10,11,14, 15,17,18 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | P | P | P | P | P | 3 | P | P | P | P | | 4,13 |
| Cardiac Pediatric | P | P | P | P | P | 3 | P | P | P | P | | 4,13 |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | P | P | P | P | P | 3 | P | | | | | 4,13 |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | P | P | 2 | P | P | P | | | 4,5,6,7,8,9,10,11,14, 15,17,18 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducers: K133761, K123992, K121422 and K103629

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| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PST-25BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | P | P | 3 | P | P | P | | | 11 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | 3 | P | P | P | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | P | 3 | P | P | P | | | |
| Adult Cephalic | P | P | P | P | P | 3 | P | P | P | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | P | P | P | P | P | 3 | P | P | P | P | | 4,13 |
| Cardiac Pediatric | P | P | P | P | P | 3 | P | P | P | P | | 4,13 |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

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|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PST-30BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | | |
| Abdominal | P | P | P | P | P | 3 | P | P | P | | | 11 | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | 3 | P | P | P | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | P | 3 | P | P | P | | | | |
| Adult Cephalic | P | P | P | P | P | 3 | P | P | P | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | P | P | P | P | P | 3 | P | P | P | P | | 4,13 | |
| Cardiac Pediatric | P | P | P | P | P | 3 | P | P | P | P | | 4,13 | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PST-50BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | | |
| Abdominal | P | P | P | P | P | 3 | P | P | P | | | 11 | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | 3 | P | P | P | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | P | 3 | P | P | P | | | | |
| Adult Cephalic | P | P | P | P | P | 3 | P | P | P | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | P | P | P | P | P | 3 | P | P | P | P | | 4,13 | |
| Cardiac Pediatric | P | P | P | P | P | 3 | P | P | P | P | | 4,13 | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PST-65AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | | |
| Abdominal | P | P | P | P | P | 3 | P | P | P | | | 11 | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | 3 | P | P | P | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | P | 3 | P | P | P | | | | |
| Adult Cephalic | P | P | P | P | P | 3 | P | P | P | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | P | P | P | P | P | 3 | P | P | P | P | | 4,13 | |
| Cardiac Pediatric | P | P | P | P | P | 3 | P | P | P | P | | 4,13 | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-375BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | P | P | | | 5,7 | |
| Abdominal | P | P | P | | P | 2 | P | P | P | | | 5,7,11,12,15,16,18 | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | P | P | | | 5, 7,12,15,18 | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-375SC

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|---------------|---------------------|-----|--------------|-------|--------|----|--------------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify)* | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | N | N | N | | N | 2 | N | N | N | | | 5,7 |
| Abdominal | N | N | N | | N | 2 | N | N | N | | | 5,7,11,12,15,16,18 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | N | N | N | | N | 2 | N | N | N | | | 5,7,12,15,18 |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: N/A

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-375MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 |
| Abdominal | P | P | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | P | P | | | 5, 7,18 |
| Abdominal | P | P | P | | P | 2 | P | P | P | | | 5, 7,12,18 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | P | P | | | 5, 7,12,18 |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-382MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | P | P | | P | 5,7,9 | |
| Abdominal | P | P | P | | P | 2 | P | P | P | | P | 5,7,9 | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | P | P | | P | 5,7,9 | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-661VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|----------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | | |
| Trans-rectal | P | P | P | | P | 2 | P | P | P | | | 4,5,7,11 | |
| Trans-vaginal | P | P | P | | P | 2 | P | P | P | | | 4,5,7,11 | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-781VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-------------------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | | |
| Trans-rectal | P | P | P | | P | 2 | P | P | P | | | 4,5,7,11,12,15,18 | |
| Trans-vaginal | P | P | P | | P | 2 | P | P | P | | | 4,5,7,11,12,15,18 | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-674BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | P | P | | | 5,7,14,15 | |
| Abdominal | P | P | P | | P | 2 | P | P | P | | | 5,7,14,15 | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | P | P | | | 5,7,14,15 | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-675MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|------------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 | |
| Abdominal | P | P | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-675MVL

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | N | N | N | | N | 2 | N | N | N | | N | 5,7,8,9,10 |
| Abdominal | N | N | N | | N | 2 | N | N | N | | N | 5,7,8,9,10 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | N | N | N | | N | 2 | N | N | N | | N | 5,7,8,9,10 |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: N/A

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-681MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | P | P | P | | P | 2 | P | P | P | | P | 4,5,7,9,11 |
| Trans-vaginal | P | P | P | | P | 2 | P | P | P | | P | 4,5,7,9,11 |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
 Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-712BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 300, Aplio 400, Aplio 500 V5.0Transducer: PVT-745BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Abdominal) | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-745BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Abdominal) | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-745BTv

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Abdominal) | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-770RT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | P | P | P | | P | 2 | P | P | P | | | 4,5,7,11 |
| Trans-vaginal | P | P | P | | P | 2 | P | P | P | | | 4,5,7,11 |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-604AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | P | P | | | 5,7,17 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | P | P | | | 5,7,17 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | P | P | | | 5,7,17 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | P | P | | | 5,7,17 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-704AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | P | P | | | 5,7,17 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | P | P | | | 5,7,17 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | P | P | | | 5,7,17 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-704SBT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | P | P | | | 5,7,14,15,17 | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | P | P | | | 5,7,14,15,17 | |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | P | P | | | 5,7,14,15,17 | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | P | P | | | 5,7,14,15,17 | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-705BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|---------------|---------------------|-----|--------------|-------|--------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify)* | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | N | N | N | | N | 2 | N | N | N | | | 5,7,15,17 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | N | N | N | | N | 2 | N | N | N | | | 5,7,15,17 |
| Musculo-skeletal (Superficial) | N | N | N | | N | 2 | N | N | N | | | 5,7,15,17 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | N | N | N | | N | 2 | N | N | N | | | 5,7,15,17 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: N/A

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-705BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Abdominal) | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PVT-705BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Abdominal) | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | P | P | | | 5,6,7,11,17 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | P | P | | | 5,6,7,11,17 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | P | P | | | 5,6,7,11,17 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | P | P | | | 5,6,7,11,17 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-1005BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|----------|------------|------------|--------------------------|--|------------|--------------------------|--------------|-------------------|-----------|-----------------------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combine d (Specify *) | THI | Dynami c Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | P | P | | | 5,6,7,11,12,14,15, 17,18 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | P | P | | | 5,6,7,11,12,14,15, 17,18 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | P | P | | | 5,6,7,11,12,14,15, 17,18 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | P | P | | | 5,6,7,11,12,14,15, 17,18 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-1202S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | P | P | P | | P | 2 | P | | P | | | 4,5,11 |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | | P | | | 4,5,11 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | | P | | | 4,5,11 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | | P | | | 4,5,11 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | | P | | | 4,5,11 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-1204BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|------------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | P | P | | | 4,5,6,7,11,15,17 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | P | P | | | 4,5,6,7,11,15,17 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | P | P | | | 4,5,6,7,11,15,17 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | P | P | | | 4,5,6,7,11,15,17 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-1204BX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | P | P | | | 5,7,15,17 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | P | P | | | 5,7,15,17 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | P | P | | | 5,7,15,17 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | P | P | | | 5,7,15,17 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PLT-1204MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PET-508MA

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---------------------------------|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | P | P | P | P | P | 3 | P | | | | | 4,13 |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PET-510MB

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | P | P | P | P | P | 3 | P | | | | | 4,13 | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PET-512MC

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | P | P | P | P | P | 3 | P | | | | | 4,13 | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K103629

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PET-805LA

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-------|--------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other | [Note] |
| Ophthalmic | | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | | |
| Laparoscopic | N | N | N | | N | 2 | N | N | N | | | 5,7 | |
| Pediatric | | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: N/A

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PC-20M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | P | | | | | | | | |
| Cardiac Pediatric | | | | P | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | P | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
| Note 1 Small organ includes thyroid, breast and testicle | Note 7 Precision Imaging | Note 13 2D WMT |
| Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD | Note 8 STIC | Note 14 Boost |
| Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD | Note 9 3D Color (Volume Color) | Note 15 SMI |
| Note 4 TDI | Note 10 STIC Color | Note 16 Shear wave |
| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

System: Aplio 500, Aplio 400, Aplio 300 V5.0Transducer: PC-50M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|--|-------------------|---|-----|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|--------------|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | P | | | | | | | | |
| Cardiac Pediatric | | | | P | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | P | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K133761

| | | |
|--|--------------------------------|--------------------------|
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| Note 5 ApliPure | Note 11 Elastography | Note 17 BEAM |
| Note 6 MicroPure | Note 12 Fusion | Note 18 Smart Navigation |

Prescription Use Only (Per 21 CFR 801.109)

510(k) SUMMARY

1. SUBMITTER'S NAME:

Toshiba Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi-ken, Japan 324-8550

2. OFFICIAL CORRESPONDENT

Akinori Hatanaka

3. ESTABLISHMENT REGISTRATION:

9614698

4. CONTACT PERSON:

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Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc
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Tustin, CA 92780
(714) 669-7459

5. Date Prepared:

May 27, 2014

6. TRADE NAME(S):

Diagnostic Ultrasound System
Aplio 500 Model TUS-A500 V5.0
Aplio 400 Model TUS-A400 V5.0
Aplio 300 Model TUS-A300 V5.0

7. COMMON NAME:

System, Diagnostic Ultrasound

8. DEVICE CLASSIFICATION:

Class II
Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [per 21 CFR 892.1550]
Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [per 21 CFR 892.1560]
Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [per 21 CFR 892.1570]

9. PREDICATE DEVICE:

| Product | Marketed by | 510(k) Number | Clearance Date |
|---|-------------------------------------|---------------|-------------------|
| Aplio 500/400/300 Diagnostic Ultrasound System V4.0 | Toshiba America Medical Systems | K133761 | April 22, 2014 |
| AIXPLORER Ultrasound System | SuperSonic Imagine, S.A. | K112255 | August 28, 2012 |
| GE Logiq E9 BT2010 Diagnostic Ultrasound System | GE Healthcare | K092271 | November 17, 2009 |
| Electromagnetic Tracking System | CIVCO Medical Instruments Co., Inc. | K092619 | November 13, 2009 |
| MicroMaxx High Resolution Ultrasound System (C3 Series) | SonoSite, Inc. | K053069 | February 24, 2006 |

10. REASON FOR SUBMISSION:

Modification of a cleared device

11. DEVICE DESCRIPTION:

The Aplio 500 Model TUS-A500, Aplio 400 Model TUS-A400 and Aplio 300 Model TUS-A300 are mobile diagnostic ultrasound systems. These systems are Track 3 devices that employ a wide array of probes including flat linear array, convex linear array, and sector array with frequency ranges between approximately 2 MHz to 12 MHz.

12. INDICATIONS FOR USE:

The **Diagnostic Ultrasound System Aplio 500 Model TUS-A500, Aplio 400 Model TUS-A400 And Aplio 300 Model TUS-A300** is indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, musculo-skeletal (both conventional and superficial) and laparoscopic.

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aplio 500/400/300 V4.0 Diagnostic Ultrasound System, 510(k) cleared under K133761, marketed by Toshiba America Medical Systems. The **Aplio 500 Model TUS-A500 Version 5.0, Aplio 400 Model TUS-A400 Version 5.0 and Aplio 300 Model TUS-A300 Version 5.0** functions in a manner similar to and is intended for the same use as the predicate devices referenced within this submission. The subject device includes modifications to the cleared device which improve upon image quality and existing features (Needle Enhancement). Also, new features determined to be substantially equivalent to features cleared under the predicate devices referenced within this submission including Shear wave and Smart Navigation and four new transducers (one of

which is indicated for laparoscopic use) are being added to the subject device. A comparison table is included in this submission which details the similarities and differences between the predicate devices and the subject device.

14. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 (2005), IEC 60601-1-2:2007, IEC 60601-2-37 (2007), IEC 62304 (2006), AIUM RTD2-2004 Output Display and ISO 10993-1 standards.

15. TESTING

Risk Analysis, Verification/Validation testing conducted through bench testing.

Performance Testing – Bench

Three studies were conducted to demonstrate that the new features being implemented to the subject device performed as intended. One study compared an existing imaging mode with the needle enhancement feature and confirmed that the subject device improves needle visualization. Another study confirmed that the subject device accurately measured the shear wave speed and elasticity of known targets within an elasticity phantom while a third study demonstrated that the use of Smart Navigation successfully navigates needles to targets at various depths using a projected path displayed on the system.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document” issued on May 11, 2005, is also included as part of this submission.

Additionally, testing of the modified system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices.

16. CONCLUSION

The modifications incorporated into the **Aplio 500 Model TUS-A500 Version 5.0, Aplio 400 Model TUS-A400 Version 5.0 and Aplio 300 Model TUS-A300 Version 5.0** do not change the intended use of the device. Based upon bench testing, successful completion of software validation, application of risk management and design controls, it is concluded that this device is safe and effective for its intended use.